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| 10/766,705 | 01/27/2004 | Steffen Leonhardt | 71186 | 3838 |
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| MCGLEW & TUTTLE, PC P.O. BOX 9227 SCARBOROUGH STATION SCARBOROUGH, NY 10510-9227 | | | NGUYEN, HUONG Q | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,705

Applicant(s)

LEONHARDT ET AL. ✓

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,11,16-18,20 and 25-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,11,16-18,20 and 25-47 is/are rejected.
- 7) ☒ Claim(s) 20,28,38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 6/20/2006. Claims 1 and 16-18 are amended. Claims 2, 4, 6-10, 12-15, 19, and 21-24 are canceled. Claims 25-47 are new. **Claims 1, 3, 5, 11, 16-18, 20, and 25-47** are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 26-47** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, **Claim 26** recites that said electrode feed lines have a length between electrodes that is greater than a length of said elastic tubes in a non stretched state. Although the specification discloses that the electrode belt is capable of stretching (§0051), the specification does not provide for any disclosure of the specific length of said electrode feed lines, thus rendering said length as new matter within Claim 26.

Claim Objections

4. **Claim 38** is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This is due to the fact that Claim 38 is an exact copy of **Claim 37**.

5. **Claims 20 and 28** are objected to because of the following informalities: “strands” should be changed to “tubes” as previously done with Claims 16-18 to maintain consistency of language. Also “said outer” should be “an outer” to avoid lack of antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1, 3, 5, 16-18, and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch (US Pat No. 5313952) in view of Hallon et al (US Pat No. 4751928).

8. In regards to **Claims 1 and 25**, Hoch discloses an electrode belt (10) comprising:

(a) a belt material of foam (20), and cloth backing strips (22, 24) (Col.2, line 64-65), wherein cloth is capable of being bent or flexed, thus constituting said belt as elastic in some sections, wherein said electrode belt fully surrounding a test subject over the circumference of the body, best seen in Figure 1 (Col.2, line 2-4);

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(b) at least two electrodes, referred to as "disk pad" (16), on said belt material as shown in Figure 1 (Col.3, line 8);

(c) electrode feed lines, referred to as "probe" (50), which extend from said electrodes (Col.3, line 24);

(d) a feed line, referred to as "coupling wire" (54), connected to said electrode feed line from a feed point, referred to as "probe support element" (52), best seen in Figure 2 (Col.3, line 23-27).

9. Hoch discloses said electrode belt with at least two electrodes, but does not disclose said belt with at least 16 electrodes nor said electrode feed lines integrated within said belt material. Hallon et al disclose an electrode belt with at least 35 electrodes for proper use (Col.2, line 36-40). Hallon et al also disclose said electrode belt with electrode feed lines, referred to as "conductors" (7), integrated within belt material to protect said electrode feed lines from damage during use (Col.2, line 27-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include at least 16 electrodes as well as integrate said electrode feed lines within said belt material, as taught by Hallon et al, with the electrode belt of Hoch, to allow for proper use and protect said electrode feed lines from damage, respectively.

10. In regards to **Claim 3**, Hoch discloses the electrodes arranged at equally spaced locations from one another on the belt material, as seen in Figure 1, as the nature of the belt allows for any desired arrangement of said electrodes (Col.2, line 15-17).

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11. In regards to **Claim 5**, Hoch discloses said belt material having electrode feed lines (explained above) but does not disclose said belt and associated electrode feed lines forming plural belt segments. Hallon et al disclose an electrode belt containing a plurality of electrodes arranged in rows as an effective arrangement for such numerous electrodes, shown in Figure 3. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine such electrode arrangement, as taught by Hallon et al, when using a multitude of electrodes (i.e. at least 16), because a large number of electrodes lends itself naturally to such arrangement.

12. Accordingly, a belt comprising of numerous rows inherently forms plural belt segments, wherein a segment is defined as any of the parts into which something can be divided, wherein in the instant case, a segment is defined as one electrode row of the belt surrounding the patient. Thus, it is said that the belt material having electrode feed lines forms plural belt segments with one or more electrodes arranged on the individual belt segments.

13. In regards to **Claims 16-18**, Hoch in combination with Hallon et al disclose said electrode belt comprising three or more tubes which extend in parallel and are connected section by section via a tube mounting piece, wherein said electrode feed lines inherently consist of electrical wiring contained within hollow tubular insulation, as is required of all electrical wires, wherein said tubular insulation are tubes that extend and can be positioned in parallel due to the adjustable nature of said electrode belt of Hoch. Furthermore, Hoch discloses said electrodes, which are attached to said electrode feed lines, attached to said belt at a tube mounting piece, referred to as "apertures" (26), best seen in Figure 1 (Col.2, 65-66). Therefore, it is said that said

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tubes are connected section by section via said tube mounting piece by virtue of their attachment to the electrodes themselves.

14. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Kristbjarnarson et al (US Pat No. 6461307). Hoch in combination with Hallon et al disclose an electrode belt with feed points arranged symmetrically in relation to one another but do not disclose the belt material split into two sections of approximately equal size. Kristbjarnarson et al disclose a sensor assembly comprising of at least two segments, referred to as “ribbon” (10), each segment having a belt closure or “latching mechanism” (332) (Col.6, line 49-50, 60-63) shown in Figure 1, to allow secure attachment of the ribbon to the body while allowing flexibility in sizing for different patients (Col.7, line 2-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the electrode belt of Hoch as modified by Hallon et al to split the belt material into two sections of approximately equal size, as taught by Kristbjarnarson et al, to promote ease of use and sizing for different patients.

15. **Claims 26-27, 29-32, 34, 36, 39, 40, and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Akiva (US Pat No. 6205346).

16. In regards to **Claims 26 and 43**, Hoch in combination with Hallon et al disclose an electrode belt comprising one or more elastic tubes with 16 or more electrodes positioned on said electrode belt and electrode feed lines extending within one or more hollow elastic tubes, as well

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as a primary connection line joined to said electrode feed lines at one or more primary connection sites on said electrode belt as explained above (see Claim 1, 16-18, and 25).

17. However, Hoch in combination with Hallon et al do not disclose said electrode feed lines having a length between electrodes that is greater than a length of said elastic tubes in a nonstretched state. Akiva teaches that analogous electrode feed lines, referred to as "conductors" (17a), contained within analogous elastic tubes, referred to as "envelope" (17c), and connected to electrodes (Col.2, line 49-52), may be disposed in a loop-like pattern, wherein said electrode feed lines are longer than the length of said elastic tubes, as seen in Figure 1, to allow for stretching of said electrode feed lines without causing damage (Col.2, line 30-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispose the electrode feed lines of the electrode belt of Hoch as modified by Hallon et al, in the loop-like pattern as taught by Akiva, to provide an effective way to allow stretching without incurring damages to said electrode feed lines.

18. In regards to **Claims 27 and 29**, Hoch in combination with Hallon et al disclose said electrode belt comprises three or more tubes that extend in parallel and connected section by section by a tube mounting piece with said electrodes arranged on said tube mounting piece, as explained in the rejection of Claims 16-18.

19. In regards to **Claim 30 and 36**, Hoch in combination with Hallon et al disclose said electrode belt and said electrode feed lines form plural belt segments with one or more of said

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electrodes arranged on individual belt segments, as discussed in the rejection of Claim 5 above, as well as said electrodes arranged at equal distances from each other within said belt segments.

20. In regards to **Claim 31**, Hoch discloses said electrodes arranged at equally spaced locations from one another on said electrode belt, as reasoned in the rejection of Claim 3 above.

21. In regards to **Claim 32**, Hoch discloses shaped elements, referred to as “body engaging surface” (36), corresponding to at least two electrodes, which inherently provide padding for the at least two adjacent electrodes at the position of placement, such as a sternal or spinal depression of a test subject (Col.5, line 9).

22. In regards to **Claim 34**, Hoch discloses a belt closure, referred to as “attachment mechanism” (28), provided between two adjacent electrodes as seen in Figure 1 (Col.3, line 2-7).

23. In regards to **Claims 39-40**, Hoch discloses said shaped elements (36) corresponding to the at least two electrodes, as one or more of said electrodes as projections bulging forward, best seen in Figure 1 (Col.3, line 8-10).

24. **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Akiva, and even further in view of Epley (US Pub No. 20040097839).

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25. Hoch as modified by Hallon et al and Akiva disclose an electrode belt but do not disclose silicone as the belt material. Epley discloses a device comprising of sensors, attached to the patient by a belt, referred to as “band” (26) best seen in Figure 1, comprising of silicone for maintaining a high level of friction to secure said belt (§0043). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the electrode belt of Hoch as modified by Hallon et al and Akiva out of silicone, as taught by Epley, to ensure good frictional contact between the belt and patient for secure use.

26. **Claims 35 and 37-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Akiva, and even further in view of Kristbjarnarson et al (US Pat No. 6461307).

27. In regards to **Claim 35**, Hoch in combination with Hallon et al and Akiva disclose an electrode belt with a belt closure for at least one belt segment but do not disclose said electrode belt with multiple belt closures. Kristbjarnarson et al disclose a sensor assembly comprising of at least two segments, referred to as “ribbon” (10), each segment having a belt closure or “latching mechanism” (332) (Col.6, line 49-50, 60-63) shown in Figure 1, to allow secure attachment of the ribbon to the body while allowing flexibility in sizing for different patients (Col.7, line 2-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a belt closure for each belt segment, as taught by Kristbjarnarson et al, on the electrode belt of Hoch as modified by Hallon et al and Akiva, to promote ease of use and sizing for different patients.

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28. Similarly, in regards to **Claims 37-38**, as Hoch as modified by Hallon et al and Akiva, further modified by Kristbjarnarson et al have disclosed an electrode belt with feed points and multiple belt closures, it would be obvious to arrange such feed points at any desired location, such as on said belt closures, as any arrangement of parts is within the scope of the electrode belt disclosed by Hoch et al (Col.4, line 31-33).

29. **Claims 41-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Akiva, and even further in view of Atlas (US Pat No. 6353396).

30. Hoch as modified by Hallon et al and Akiva disclose an electrode belt with shaped elements but do not disclose said shaped elements comprising cavities filled with a medium and closed by an elastic membrane, wherein said medium are liquids, gels, or gases. Atlas discloses shaped elements, referred to as “air cushions” (13, 15) placed on electrodes (12) to provide padding as well as anti-shock protection (Col.5, line 58-64), best seen in Figure 3, wherein air cushions are commonly known to comprise of a cavity closed by an elastic membrane and filled with a gas medium. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shaped elements of the electrode belt disclosed by Hoch as modified by Hallon et al and Akiva, to be cavities closed by an elastic membrane and filled with a medium of liquid, gel, or gas, as taught by Atlas, to provide padding for the electrode and the patient as well as exhibit shock absorbing capabilities for better functioning of the device.

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31. **Claims 44-45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Akiva, and even further in view of Fry et al (US Pat No. 4539640).

32. Hoch in combination with Hallon et al and Akiva disclose an electrode belt but do not disclose said belt with a coding means. Fry et al disclose an electrode belt with a coding means, referred to as "male connector" (13), best seen in Figure 1, a plug type on an electronic unit, referred to as "data acquisition apparatus" (16) (Col.5, line 56-68), wherein said apparatus includes a digital/analog electronic unit (126), as shown in Figure 4, wherein said coding means is used to relay information gathered by the belt. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a coding means such as a plug type connection on a digital/analog electronic unit, as taught by Fry et al, with the electrode belt of Hoch as modified by Hallon et al and Akiva, to provide an effective means of relaying information about the belt.

33. **Claims 46-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoch in view of Hallon et al, further in view of Akiva and Fry et al, and even further Asai et al (US Pat No. 4681118).

34. Hoch in combination with Hallon et al and Akiva disclose an electrode belt but do not disclose an evaluating unit. Fry et al disclose an evaluating unit (16) used to analyze information gathered from said belt. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an evaluating unit, as taught by Fry et al, with the electrode belt of Hoch as modified by Hallon et al and Akiva, to provide an effective data

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analysis means coupled to said belt. However, Hoch, Hallon et al, Akiva, and Fry et al do not disclose a wireless means for wireless communication between said electrode belt and said evaluating unit.

35. Asai et al disclose an electrode assembly comprising a wireless transmitter (15) for wireless communication with a remotely placed receiver to provide a device that does not require the use of wires, allowing the receiver to be placed at any desired distance for greater convenience of use (Col.4, line 14-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a wireless means such as a transmitter, as taught by Asai et al, with the electrode belt and evaluating unit of Hoch as modified by Hallon et al, Akiva, and Fry et al, to provide a more convenient method of transmitting data from the electrode belt to an evaluating unit.

Allowable Subject Matter

36. **Claims 20 and 28** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

37. Applicant's arguments with respect to **Claims 1, 3, 5, 11, 16-18, 20, and 25-47** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

38. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

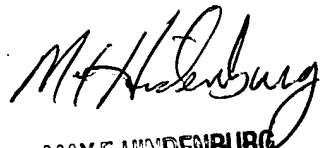
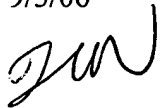
39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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